

REMARKS

Claims 1, 3-4, 6-28, 30-31, 33-36, and 46-57 are pending in the present Application, with claims 10-27 and 46-54 withdrawn as directed to nonelected subject matter.

Claims 3, 8-9, 30, 35-36, and 58-59 are cancelled, claims 1, 28, and 55 are amended, leaving Claims 1, 4, 6-7, 28, 31, 33-34, and 55-57 for consideration upon entry of the present Amendment.

Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

Examiner Interview

Applicants thank the Examiner for the courtesy of a telephonic interview with Applicants' representative, Sandra Shaner, on June 28, 2011. Possible claim amendments were discussed with respect to the outstanding 103 rejection.

Claim Amendments

Claims 1, 28, and 55 are amended.

Support for amendments to claim 1 are found in claims 1, 3, and 9 as originally filed and in the specification at least at p. 8, lines 21-23 and Table A and p. 10, lines 15-16.

Support for amendments to claim 28 are found in claims 28, 30, and 36 as originally filed and in the specification at least at p. 8, lines 21-23 and Table A and p. 10, lines 15-16.

Support for amendments to claim 55 are found in claim 1 as originally filed and in the specification at least at p. 8, lines 21-23 and Table A and p. 10, lines 15-16.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1, 3-4, 6-9, 28, 30-31, 33-36, and 55-59 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Carpenter (US 5637344; hereinafter "Carpenter") in view of the combination of Raymont (AU 71907/96 A; hereinafter "Raymont") and Seang (WO 94/05260; hereinafter "Seang"). Applicants respectfully traverse this rejection.

Claims 3, 8-9, 30, 35-36, and 58-59 are cancelled.

“A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). To find obviousness, the Examiner must “identify a reason that would have prompted a person of ordinary skill in the art in the relevant field to combine the elements in the way the claimed new invention does.” *Id.*

With regard to the hard boiled candy composition of claims 1, 4, 6-7, and 55-56, Carpenter is generally directed to an amorphous crystalline chocolate flavored hard candy confection using air-jet milled cocoa powder with particles less than 15 μ having generally rounded edges. (Abstract) Carpenter teaches that one example of a hard candy chocolate product sold in Japan with a surface dusted with cocoa powder had a rough, coarse, sandy surface and that such characteristics are not acceptable for hard candy. (col. 1, lines 20-26) Carpenter discloses that use of air-jet-milled cocoa powders impart characteristic chocolate flavor to the hard candy without the “sandpaper texture”. (col. 9, lines 20-23) Carpenter further discloses that oil, when present in his chocolate-flavored hard candy, facilitates mixing the air-jet milled cocoa powder and the amorphous candy mass by facilitating dispersion of the air-jet milled cocoa powder and adds perceived richness to the final product and improves the texture thereof. (col. 6, lines 58-65) Carpenter discloses that the oil can be either a dairy-based oil or a vegetable oil. (col. 6, lines 60-61) Carpenter discloses that when the optional oil is added, “it is present in sufficient amounts to facilitate mixing of the air-jet milled cocoa powder with the amorphous candy mass” (col. 7, lines 37-40) and that the weight ratio of air-jet-milled cocoa powder to the oil that facilitates mixing ranges from about 1:3 to about 100:1, and more preferably 0.67:1 to 1.5:1. (col. 7, lines 42-45) For stamped products, Carpenter states that the preferred amount of oil in the hard candy should preferably be kept at less than 5% by weight, and for molded products, then the amount of oil is preferably greater than 3% by weight. (col. 8, last line bridging to col. 9, line 6)

However, Carpenter does not disclose, or even suggest, a hard boiled candy composition comprising Echinacea, having an unpleasant mouthfeel in the form of a tingling sensation as required in independent claims 1 and 55. Carpenter also does not explicitly disclose a composition with a ratio of the partially hydrogenated vegetable oils or saturated fats to Echinacea of 1.0/0.6 to 1.0/0.15 as recited in claim 1 or a composition including an amount of one

or more partially hydrogenated vegetable oils or saturated fats effective to suppress said tingling sensation or astringency characteristic of Echinacea as recited in claim 55.

Raymont is generally directed to a therapeutic compositions comprising one or more vitamins and/or provitamins, one or more amino acid metal chelates, Echinacea extract, Ginkgo biloba extract, one or more antioxidants, together with a pharmaceutically acceptable carrier vehicle. (Abstract) Raymont teaches that his particular combination of active ingredients has a significant synergistic effect, with a therapeutic effect greater than the additive effect of the various components. (p. 2, para. 2, lines 7-10) Raymont teaches that his composition may be formulated as tablets, capsules, lozenges, emulsions, solutions, and suspensions (p. 3, lines 30-31) , but does not provide any explicit examples of the composition in any formulation other than a tablet. (pp. 7-8) In Raymont's composition, the Echinacea extract can be present at 1.5-4 w/w%. (p. 6, lines 26-27)

However, Raymont does not teach or suggest a hard boiled candy composition in which an amount of from about 0.5% to about 5.0% by weight of said hard boiled candy composition of one or more partially hydrogenated vegetable oils or saturated fats, said amount being effective to suppress the tingling sensation or astringency characteristic of Echinacea, as required in claim 1. Raymont also does not explicitly disclose a composition with a ratio of the partially hydrogenated vegetable oils or saturated fats to Echinacea of 1.0/0.6 to 1.0/0.15 as recited in claim 1 or a composition including an amount of one or more partially hydrogenated vegetable oils or saturated fats effective to suppress said tingling sensation or astringency characteristic of Echinacea as recited in claim 55.

Seang discloses that his invention relates to compositions comprising a drug having its taste masked by a lipid coating contained within an aqueous polymer system for oral administration. (p. 1, lines 5-8) Seang teaches that a means of preparing drugs with an unpalatable bitter taste for oral administration is in a granule-lipid format which are suspended in an aqueous solution immediately prior to oral administration and that in this manner, the drug is not dissolved in the mouth of the patient, but passes on to the gastrointestinal tract where it is dissolved by stomach fluids. (p. 1, lines 11-25)

Seang discloses a method of producing a stable drug composition masking a drug flavor in which a particulate drug is mixed with a lipid below the temperature of significant drug-

degradation, and to this drug-lipid mixture is added an emulsifier, a polymer solution and a dilution solution to form the stable taste-masked drug composition. (p. 2, line 29 to p. 3, line 2) Seang discloses an alternative method in which a mixture of a lipid and an emulsifier are heated until brought into the molten state, the molten mixture is cooled to a temperature below the temperature of significant drug-degradation and then admixed with the particulate drug to form a flavor masked drug/lipid dispersion, to which a polymer solution is added to form a concentrated drug composition, and finally a dilution solution is added to form the final drug composition. (p. 3, lines 3-15) Note that the drug compositions of Seang are dispersions (p. 3, lines 17-18), rather than a solid composition as in the claimed invention. Seang teaches the drug is selected from cimetidine, ranitidine, ibuprofen, acetaminophen, and erythromycin. (p. 3, lines 15-17)

Seang discloses that the lipid can be a hydrogenated or partially hydrogenate oil such as cottonseed oil, castrol oil, and coconut oil. (p. 6, lines 8-9) Seang teaches that the amount of lipid ranges from 25-200% of the amount of drug employed, but is preferably in a lipid:drug ratio of 1:1, and the maximum amount of lipid added to a 10 cc solution of the drug composition is about 800 mg. (p. 8, lines 8-12)

However, Seang does not teach or suggest a hard boiled candy composition in which an amount of from about 0.5% to about 5.0% by weight of said hard boiled candy composition of one or more partially hydrogenated vegetable oils or saturated fats, said amount being effective to suppress the tingling sensation or astringency characteristic of Echinacea, as required in claim 1. Seang also does not explicitly disclose a composition with a ratio of the partially hydrogenated vegetable oils or saturated fats to Echinacea of 1.0/0.6 to 1.0/0.15 as recited in claim 1 or a composition including an amount of one or more partially hydrogenated vegetable oils or saturated fats effective to suppress said tingling sensation or astringency characteristic of Echinacea as recited in claim 55.

Thus applicants contend that all elements of the compositions of independent claims 1 and 55 are not disclosed or suggested by the cited combination of references and therefore independent claims 1 and 55 are not obvious over the combination of Carpenter, Raymont, and Seang.

For all the above reasons applicants contend that claims 1, 4, 6-7, and 55-56 are not obvious over the combination of Carpenter, Raymont, and Seang.

Even if a prima facie case of obviousness were conceded, which it is not, it is respectfully submitted that applicant's invention is not obvious because the particular combination of claimed elements results in unexpectedly beneficial properties. An applicant can rebut a prima facie case of obviousness by presenting comparative test data showing that the claimed invention possesses unexpectedly improved properties or properties that the prior art does not have. *In re Dillon*, 919 F.2d 688, 692-93, 16 U.S.P.Q.2d 1987, 1901 (Fed. Cir. 1990).

Applicants show in Example 1 (pp. 8-10) and Example 2 (p. 10) of the instant specification an unexpectedly large suppression of the tingling sensation of a representative botanical, Echinacea, alone or in combination with Siberian Ginseng, by addition of a partially hydrogenated vegetable oil or saturated fat to the hard boiled candy compositions. See Table A (p. 8) showing percent reduction in the tingling mouthfeel due to Echinacea in the compositions of greater than 57.5 % compared to control Echinacea-containing compositions lacking any partially hydrogenated vegetable oil or saturated fat. Mouthfeel evaluations of the compositions were made by an eight member professional descriptive panel, trained to measure differences in sensory attribute intensities over time, who performed three replicate evaluations for each sample. (p. 9, lines 6-16) The results of the panel test show significant reduction in mouthfeel effects for the inventive examples in comparison with the corresponding controls. (p. 10, lines 1-4). For example in Table A, mouthfeel of exemplary inventive composition A (2.8% palm kernel oil; 1:0.6 oil: Echinacea ratio) is compared to that of composition 1 (no partially hydrogenated vegetable oils or saturated fats) and was determined by the panel to have a 65% reduction in mouthfeel as compared to control composition 1 or mouthfeel of exemplary inventive compositions C (4.98%; 1:0.17 oil: Echinacea ratio) and D (1.42%; 1:0.6 oil: Echinacea ratio) are compared to that of control composition 2, lacking any partially hydrogenated vegetable oils or saturated fats and were determined by the panel to have reductions in mouthfeel as compared to control composition 2 of 71.3% and 57.5%, respectively.

As the claimed compositions show unexpectedly superior reduction in the unpleasant tingling sensation of Echinacea in the hard-boiled candy compositions, Applicants contend the hard boiled candy compositions of claims 1, 4, 6-9, and 55-56 are not obvious over the combination of Carpenter, Raymont, and Seang.

Reconsideration and withdrawal of the rejection of claims 1, 3-4, 6-7, and 55-56 are requested.

With respect to method claims 28, 31, 33-34, and 57, Carpenter does not disclose or suggest adding to a confectionary base, comprised of a mixture of at least one sugar and at least one carbohydrate bulking agent which is kept in an amorphous or glassy condition, and Echinacea one or more partially hydrogenated vegetable oils or saturated fats in an amount effective to suppress the tingling sensation or astringency characteristic of Echinacea in the hard boiled candy composition. Carpenter also does not explicitly disclose a ratio of the partially hydrogenated vegetable oils or saturated fats to Echinacea of 1.0/0.6 to 1.0/0.15 as recited in claim 28.

With respect to independent method claim 28, Raymont does not provide any details as to how to make his compositions.

With respect to independent method claim 28, Seang discloses a method of producing a stable drug composition, in the form of a liquid dispersion and masking a drug flavor, in which a particulate drug is mixed with a lipid below the temperature of significant drug-degradation, and to this drug-lipid mixture is added an emulsifier, a polymer solution and a dilution solution to form the stable taste-masked drug composition. (p. 2, line 29 to p. 3, line 2) Seang discloses an alternative method in which a mixture of a lipid and an emulsifier are heated until brought into the molten state, the molten mixture is cooled to a temperature below the temperature of significant drug-degradation and then admixed with the particulate drug to form a flavor masked drug/lipid dispersion, to which a polymer solution is added to form a concentrated drug composition, and finally a dilution solution is added to form the final drug composition. (p. 3, lines 3-15)

However, Seang does not disclose or suggest adding to a confectionary base, comprised of a mixture of at least one sugar and at least one carbohydrate bulking agent which is kept in an amorphous or glassy condition, and Echinacea, one or more partially hydrogenated vegetable oils or saturated fats in an amount effective to suppress said unpleasant mouthfeel in the form of a tingling sensation of the Echinacea in the hard boiled candy composition. Seang also does not explicitly disclose a ratio of the partially hydrogenated vegetable oils or saturated fats to Echinacea of 1.0/0.6 to 1.0/0.15 as recited in claim 28.

As all elements of independent method claim 28 are not disclosed or suggested by the combination of Carpenter, Raymont, and Seang, method claim 28 and its dependent claims are not obvious over the combination of references.

For all the above reasons, claims 28, 30-31, 33-34, and 57 are not obvious over the combination of references.

Further, as discussed above with respect to the hard boiled candy compositions of independent claims 1 and 55, such compositions made by the claimed method are shown to have unexpectedly superior reduction in the unpleasant tingling sensation of Echinacea associated with compositions lacking partially hydrogenated vegetable oils or saturated fats. As the method produces unexpectedly superior hard boiled candy compositions, method claims 28, 30-31, 33-34, and 57 are not obvious over the combination of Carpenter, Raymont, and Seang.

For all the above reasons, reconsideration and withdrawal of the rejection of claims 28, 30-31, 33-36, and 57 over the combination of Carpenter, Raymont, and Seang are requested.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance are requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

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